



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Carmen Rodia

From: Eric Bohnenblust, Ph.D., Entomologist

Secondary Review: Jennifer Urbanski, PhD, Biologist

Date: February 5, 2015

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 425394, 425391, 425392, 425393

Decision no.: 490524, 490525, 490526, 490527

Submission no: 963730, 963727, 963728, 963729

Action code: R310, R310.1, R310.1, R310.1

Product Name: RF2201-08 DFB Block, RF2204-01 DFB Block, RF2203-02 DFB Block, RF2202-04 DFB Block

EPA Reg. No or File Symbol: 89459-O, 89459-A, 89459-T, 89459-I

Formulation Type: Mineral Supplement Feed-Through containing Diflubenzuron

Ingredients statement from the label with PC codes included:

89459-O: Diflubenzuron 0.08% PC: 108201

89459-A: Diflubenzuron 0.01% PC: 108201

89459-T: Diflubenzuron 0.02% PC: 108201

89459-I: Diflubenzuron 0.04% PC: 108201

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² as appropriate): 0.1 mg/kg/day for cattle, 0.15 mg/kg/day on equine species

Use Patterns: Animal Feed-through

I. Action Requested: Review of data to support label claims against fecal flies on horses for diflubenzuron and response to registrant on a house fly study.

II. Background: An updated data matrix was submitted with data to support claims against various fly species for a diflubenzuron feedthrough for equine species, and additional information was provided by the registrant to allow for adequate evaluation of MRID # 49498402.

III. MRID Summary:

46230604. Efficacy of diflubenzuron as an oral larvacide treatment for control of fly larvae in manure of treated horses.

(1) **Conclusion: Cited.** This study was reviewed previously and found to be acceptable to support efficacy claims against stable fly and house fly larvae at the rate of 0.15 mg diflubenzuron/kg body weight/day. This study in addition to MRID #'s 46275501, 46230601, 46230602, and 46230603 which were previously reviewed on September 11, 2014, support efficacy claims for house fly and stable fly control at the rate of 0.15 mg diflubenzuron/kg body weight/day.

Response to registrants request to reconsider conclusions of the previous review of MRID # 49498402 based on the new information they provided:

Registrant's Email Response January 30, 2015: I noted that the title for the efficacy study in the DER is incorrect for MRID 49498402. It should be Efficacy of an Insect Growth Regulator for the Control of House Flies. I believe that the most critical point of clarification is that the study with MRID # 49498402 was a house fly study as opposed to a horn fly study. Additional clarification is that treatment groups 1 and 2 of that study were the grade of diflubenzuron that would be used to formulate into these block formulations. The diflubenzuron in group 3 of this study was of a different technical spec than what will be used for these products. Efficacy for groups 1 & 2 was 90% or higher for all test days. Efficacy for group 3 was below 72.5% for all test days, which led to the realization that the grade of technical diflubenzuron used is critical to efficacy. Can you reconsider accepting the house fly claim on this basis.

The registrant sent through email more information with regard to the dose and technical grade of diflubenzuron used in MRID # 49498402 on February 4, 2015. Both emails referenced above are attached to this review.

Review of this updated material:

The information provided shows that the dose of diflubenzuron given to cattle was 0.1 mg diflubenzuron/kg body weight/day. According to the email sent by the registrant, the technical grade of diflubenzuron used in the products under review corresponds to treatment groups 1 and 2 in MRID # 49498402. In these two treatment groups, efficacy was acceptable (> 90%), therefore this study will support efficacy claims against house flies for diflubenzuron at a rate of 0.1 mg diflubenzuron/kg body weight/day. Please note, in future studies the test substance should be used for efficacy testing, and information should be provided so that the tested substance can be adequately compared with the labeled product.

IV. RECOMMENDATIONS:

(1) Labeling: All claims efficacy claims against house flies and stable flies in manure of treated equines species are acceptable. Efficacy claims against horn flies and face flies and horses are unacceptable per Jennifer Urbanski's previous review of DPs: 421370; 421371; 421372; 421369 on September 11, 2014.

Efficacy claims against house flies in manure of treated bovine species are acceptable.

(a) **The acceptability of specific claims are listed below.**

PLEASE NOTE: the claims listed as acceptable and unacceptable in this review should be used in place of claims listed as acceptable or unacceptable on previous efficacy reviews.

The following claims are acceptable on the label for 89459-O (RF2201-08):

A nutritional)(protein)(mineral)(vitamin) supplement for (horses) (ponies) (donkeys) (and) (mules) (labeled animals) containing diflubenzuron (brand name) for continuous feeding during the fly season

A nutritional)(protein)(mineral)(vitamin) supplement for (horses) (ponies) (donkeys) (and) (mules) (labeled animals) containing diflubenzuron (brand name) for continuous feeding to (horses)(ponies)(donkeys)(and) (mules)(labeled animals) during the fly season

Prevents the emergence of house flies and stable flies from manure of treated (horses)(ponies)(donkeys)(and) (mules)(labeled animals)

Controls house flies and stable flies developing in manure of treated (horses)(ponies)(donkeys) (and)(mules)(labeled animals)

Controls flies growing in manure of treated (horses)(ponies)(donkeys) (and)(mules)(labeled animals)

Stops the development of House fly and Stable fly larvae in manure of treated (horses)(ponies)(donkeys)(and)(mules) (labeled animals)

Prevents the development of House fly and Stable fly larvae in manure of treated (horses)(ponies)(donkeys)(and)(mules) (labeled animals)

Stops the development of House fly and Stable fly larvae in manure from treated (horses)(ponies)(donkeys)(and)(mules) (labeled animals)

Prevents the development of (House fly)(Stable fly) larvae in manure from treated (horses)(ponies)(donkeys)(and)(mules) (labeled animals)

Stops the emergence of adult (House flies)(Stable flies) from manure of treated (horses)(ponies)(donkeys)(and)(mules)(labeled animals)

Prevents the emergence of adult (House flies)(Stable flies) from manure of treated (horses)(ponies)(donkeys)(and)(mules)(labeled animals)

Stops the emergence of adult (House flies)(Stable flies) from manure from treated (horses)(ponies)(donkeys)(and)(mules)(labeled animals)

Prevents the emergence of adult (House flies)(Stable flies) from manure from treated (horses)(ponies)(donkeys)(and)(mules)(labeled animals)

Solid feed supplement for (horses)(ponies)(donkeys)(and)(mules)(labeled animals) (only)

For all classes of (horses)(ponies)(donkeys)(and)(mules)(labeled animals)(only)]

A (nutritional)(protein)(mineral)(vitamin) supplement for (beef)(dairy)(cattle) containing diflubenzuron (brand name)] for continuous feeding to (beef)(dairy)(cattle) during the fly season

A (nutritional)(protein)(mineral)(vitamin) supplement containing diflubenzuron (brand name) for continuous feeding of cattle during the fly season

A (nutritional)(protein)(mineral)(vitamin) supplement for (beef)(dairy)(cattle) containing diflubenzuron (brand name) for continuous feeding during the fly season

A (nutritional)(protein)(mineral)(vitamin) supplement containing diflubenzuron (brand name)] for continuous feeding to (beef)(dairy)(cattle) during the fly season

A (nutritional)(protein)(mineral)(vitamin) supplement for (beef)(dairy) cattle containing diflubenzuron (brand name) for continuous feeding during the fly season

A (nutritional)(protein)(mineral)(vitamin) supplement for (beef)(dairy) cattle containing diflubenzuron (brand name) for continuous feeding to (beef)(dairy) cattle during the fly season

Prevents the emergence of (house fly)(Stable fly)(Face fly)(and)(Horn fly) from manure of treated cattle

(House fly) (Stable fly)(Face fly)(and)(Horn fly) larvicide for cattle

(House fly) (Stable fly)(Face fly)(and)(Horn fly) control for cattle

Controls (House fly) (Stable fly)(Face fly)(and)(Horn fly) developing in manure of treated cattle

Controls (House fly)(Stable fly)(Face fly)(and)(Horn fly) growing in manure of treated cattle

Controls (House fly) (Stable fly)(Face fly)(and)(Horn fly) developing in manure of treated cattle

Stops the development of (House fly) (Stable fly)(Face fly)(and)(Horn fly) larvae in manure of treated cattle

Prevents the development of (House fly) (Stable fly)(Face fly)(and)(Horn fly) larvae in manure of treated cattle

Stops the development of (House fly) (Stable fly)(Face fly)(and)(Horn fly) larvae in manure from treated cattle

Prevents the development of (House fly) (Stable fly)(Face fly)(and)(Horn fly) larvae in manure from treated cattle

Stops the emergence of adult (Stable flies)(Face flies)(and)(Horn flies) from manure of treated cattle

Prevents the emergence of adult (House fly) (Stable flies)(Face flies)(and)(Horn flies) from manure of treated cattle

Stops the emergence of adult (House fly) (Stable flies)(Face flies)(and)(Horn flies) from manure from treated cattle

Prevents the emergence of adult (House fly) (Stable flies)(Face flies)(and)(Horn flies) from manure from treated cattle

Prevents the formation of chitin in fly larvae's exoskeletons when they molt

Prevents the formation of chitin in fly larvae's exoskeletons when they molt resulting in their death

Prevents the formation of fly larvae's exoskeletons when they molt resulting in their death

Prevents the formation of fly larvae's exoskeletons when they molt

Contains (diflubenzuron)(brand name)

Contains (diflubenzuron)(brand name) a chitin synthesis inhibitor

Breaks the (House fly) (Stable fly)(Face fly)(and)(Horn fly) life cycle

Can be used as part of a total (House fly) (Stable fly) control program for horses) (ponies) (donkeys) (and) (mules)

Can be used as part of an integrated (House fly) (Stable fly)(Face fly)(and)(Horn fly) control program for cattle

Can be used as part of an integrated pest management program

Can be used as part of a total (House fly) (Stable fly)(Face fly)(and)(Horn fly) control program for cattle

Can be used as part of a total pest management program

Can be used as part of a complete (House fly)(Stable fly)(Face fly)(and)(Horn fly) control program for cattle

Can be used as part of a complete pest management program

Solid feed supplement for all classes of (beef) and (dairy) (cattle)

For (beef) and (dairy)(cattle)

Solid feed supplement for (beef) and (dairy)(cattle)
Solid feed supplement for (beef) and (dairy) cattle (only)
For (beef) and (dairy) cattle (only)

The following claims are unacceptable on the label for 89459-O (RF2201-08):

Helps protect your (horse)(pony)(donkey)(and)(mule)(labeled animal) from Flies when you can't be there
Protect Your (Horse)(pony)(donkey)(and)(mule)(labeled animal) from the pain of Fly Bites
Protect Your (Horse)(pony)(donkey)(and)(mule)(labeled animal) from the discomfort of Fly Bites
Protect Your (Horse)(pony)(donkey)(and)(mule)(labeled animal) from Fly Bites
- All of the above claims are unacceptable because the product does not prevent adult flies that are already present from biting the animal
Stops Flies Before They Fly - this is vague and implies a range of things including adult control which data do not support.
Reduce the Risk of Disease & Infection Transmitted by Flies – data do not support this.
Reduce the Risk of Summer Sores – data do not support this.
Clinically proven feed-thru fly control – the agency does not allow this type of claim
Highly Palatable – data do not support highly palatable.
Weather resistant – data showing weather resistance were not submitted.
Approved for lactating and pregnant mares - data need to be submitted for lactating and pregnant mares.
Can be fed to lactating and pregnant mares - data need to be submitted for lactating and pregnant mares.

(b). The following efficacy claims are acceptable on the label for 89459-A (RF2201-01), 89459-T (RF2201-02), 89459-I (RF2201-04) as follows:

A [(nutritional)(protein)(mineral)(and)(vitamin)] supplement [for (beef)(dairy)(cattle) (and) (horses) (ponies) (donkeys) (and) (mules)] containing [(diflubenzuron)(brand name)] for continuous feeding [to (beef)(dairy)(cattle) (and) (horses) (ponies) (donkeys) (and) (mules)] during the fly season
Prevents the emergence of house flies, horn flies, face flies, and stable flies from manure of treated cattle
(House fly) (Stable fly)(Face fly)(and)(Horn fly) larvicide for cattle
Controls house fly, horn fly, stable fly, and face fly larvae [(developing)(growing)] in manure of treated cattle
[(Stops)(Prevents the)] development of (House fly) (Stable fly)(Face fly)(and)(Horn fly) larvae in manure [(of)(from)] treated cattle
[(Stops)(Prevents the)] emergence of adult (House fly) (Stable flies)(Face flies)(and)(Horn flies) from manure [(of)(from)] treated cattle
Prevents the emergence of house flies and stable flies from manure of treated (horses) (ponies) (donkeys) (and) (mules)
Controls stable fly, and house fly larvae [(developing)(growing)] in manure of treated (horses) (ponies) (donkeys) (and) (mules)
[(Stops)(Prevents the)] development of (House fly) (Stable fly)(Face fly)(and)(Horn fly) larvae in manure [(of)(from)] treated (horses) (ponies) (donkeys) (and) (mules)
[(Stops)(Prevents the)] emergence of adult (House fly) (Stable flies)(Face flies)(and)(Horn flies) from manure [(of)(from)] treated (horses) (ponies) (donkeys) (and) (mules)
Contains [(diflubenzuron)(brand name) (a chitin synthesis inhibitor)]
Breaks the (House fly) (Stable fly)(Face fly)(and)(Horn fly) life cycle in cattle
Breaks the (House fly) (Stable fly) life cycle in (horses) (ponies) (donkeys) (and) (mules)
(Can be used as) part of [(an integrated) a (total) (a complete)] ((Stable fly)(House fly)control)(pest management) program for (horses) (ponies) (donkeys) (and) (mules)
(Can be used as) part of [(an integrated) a (total) (a complete)] ((Stable fly)(Face fly)(and)(Horn fly) control)(pest management) program for cattle
[Solid feed supplement] [for all classes of (beef)and(dairy)]
Prevents the formation of (chitin in) fly larvae's exoskeletons when they molt (resulting in their death)

The following efficacy claims are unacceptable on the label for 89459-A (RF2201-01), 89459-T (RF2201-02),

89459-I (RF2201-04):

Helps Protect Your [(Horse)(pony)(donkey)(and)(mule)(labeled animal)] from Flies When You Can't Be There – Already present adult flies may still bite.

Stops Flies Before They Fly – this is vague and implies a range of things including adult control which data do not support.

Reduce the Risk of Disease & Infection Transmitted by Flies – data do not support this.

Protect Your [(Horse)(pony)(donkey)(and)(mule)(labeled animal)] from the [pain, discomfort] of Fly Bites -

Already present adult flies may still bite.

Reduce the Risk of Summer Sores – data do not support this.

Clinically proven feed-thru fly control – data do not support this.

Highly palatable – data were not submitted to show that it is highly palatable.

Weather resistant - data were not submitted to show weather resistance.

[(Approved for) (Can be fed to)] lactating and pregnant mares – data need to be submitted for lactating and pregnant mares.